

Appl. No. 10/560,422
Amendment dated: September 29, 2008
Reply to OA of: July 1, 2008

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1(currently amended). A method of determining prothrombin time (PT) in a whole blood, anti-coagulated blood, blood plasma or anti-coagulated blood plasma sample comprising the steps of

a) adding a defined volume of the sample to a defined volume of a liquid reagent, or vice versa, in a vessel,

b) determining the temperature of the ~~reaction~~ mixture of a) at an ambient temperature in the range of 15°C to 45°C,

~~the steps a) and b) being performed in an optional order, followed by~~

c) determining a clotting time (CT) by registering the time from the addition in a) until a clot is detected in the vessel,

and

d) calculating the prothrombin time (PT) based on the temperature of b) and the clotting time (CT) of c), expressed as International Normalized Ratio (INR), by using the equation

$$\text{INR} = (\text{CT}/(\text{NCT}(t)))^{\text{ISI}(t)}$$

wherein

CT = the clotting time

t = the temperature,

NCT(t) = Normal Clotting Time (NCT) expressed as a function of the temperature t,

and

ISI(t) = International Sensitivity Index (ISI) expressed as a function of the temperature t.

2(original). The method according to claim 1, wherein the liquid reagent comprises two or three different reagents.

3(previously presented). The method according to claim 1, wherein the liquid reagent contains an amount of fibrinogen increasing the concentration of fibrinogen in the mixture of a) by at least 0.1 g/L and the ratio between the defined volume of the reagent and sample in a) is at least four.

4(canceled).

5(previously presented). The method according to claim 1, wherein the determination of the temperature in b) is accomplished by determining the ambient room temperature, provided that the liquid reagent is of the same temperature.

6(previously presented). The method according to claim 1, wherein the ambient temperature is in the range of 18°C to 35°C.

7(original). The method according to claim 6, wherein the ambient temperature is in the range of 30°C to 35°C.

8(canceled).

9(previously presented). The method according to claim 1, wherein the prothrombin time (PT) is obtained from a table with rows and columns where one is for various clotting times, and the other is various temperatures, and the PT is found in the intersection of clotting time and temperature.

10(previously presented). A test kit for performing an analysis according to the

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method of claim 1 comprising temperature recoding means, and one or several separate sealed vessels containing reagents for clotting one or more defined volumes whole blood, anti-coagulated blood, blood plasma or anti-coagulated blood plasma sample.

11(original). The test kit according to claim 10, wherein a reagent in a vessel contains fibrinogen in an amount that yields a final fibrinogen concentration of at least 0.1 g/L in a vessel when mixed with a sample to be tested.

12(previously presented). The test kit according to claim 10, wherein the reagents in the vessels are in lyophilized form for reconstitution with one or more defined volumes of liquid prior to use.

13(previously presented). The test kit according to claim 10, additionally comprising time registration means.

14(previously presented). The test kit according to claim 10, additionally comprising volume determining means.